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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/435,247	11/05/99	SORNASSE	T PA-0020 US

HM12/0420

Incyte Pharmaceuticals Inc  
3174 Porter Drive  
Palo Alto CA 94304

EXAMINER

PRASAD, S

ART UNIT	PAPER NUMBER
1646	4

DATE MAILED: 04/20/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/435,247	Sornasse et al.
	Examiner	Art Unit
	Sarada C Prasad	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 12 May 2000.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claims 1-20 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

15) Notice of References Cited (PTO-892)

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_

18) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

19) Notice of Informal Patent Application (PTO-152)

20) Other: \_\_\_\_\_

*Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Groups 1-516: Claims 1-6, 11-13, drawn to each of the polynucleotides of SEQ ID NO: 1-516, vector, host cell, its expression, classified in class 435, subclass 69.2.

Groups 516-1032: Claims 1, 7-9, drawn to a composition containing a plurality of polynucleotides of SEQ ID NOs: 1-516, and high throughput method for screening and detecting a library of molecules to identify a ligand for each of the polynucleotides of SEQ ID NOs: 1-516, class, subclass undeterminable.

Group 1033-1548: claims 10, drawn to a method of purifying ligands, classified in class 530, subclass 350.

Group 1549-1791: Claim 14, drawn to each of the polypeptides corresponding to SEQ ID Nos: 1-243, classified in class 530, subclass 350.

Group 1792-2034: Claims 15-17, drawn to a method of screening a library of compounds, and purifying a ligand for each of the polypeptides corresponding to polynucleotides of SEQ ID Nos: 1-243, class 435, subclass 6.

Group 2035-2794: Claims 18-20 drawn to a method of screening a sample, comprising detecting and quantifying complex formation of each of the polynucleotides of SEQ ID NOs: 1-516, and each of the polypeptides 1-243, from a patient for a disease that is pro-inflammatory or anti-inflammatory, class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions in Groups 1-516 are independent and distinct, each from the other, because

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each of the polynucleotides can only code for the corresponding polypeptide, and each of the inventions is not required for the practice of the other.

Inventions in Groups 1-516 and 1549-1791 are related as process of making and the product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polynucleotides of inventions 1-516 can be used to make the polypeptides of inventions 1549-1791 or as hybridization probes or in the making of transgenic animals, or as therapeutic agents. At the same time, the polypeptides of inventions 1549-1791 can also be made by peptide synthesizer, isolation/purification form cells and tissues. Each of the inventions can be practiced without the need for the other.

The methods of inventions 516-1032, 1033-1548, 1792-2034 and 2035-2794 are distinct which possess characteristic differences in operation and process steps and each has an independent utility, that is distinct for each invention which can not be exchanged. For example, the methods of high throughput screening of polynucleotides in inventions 516-1032 are distinct from the methods of purification of ligands for the polynucleotides inventions 1033-1548. In a similar fashion, a search for the methods of screening to identify ligands for proteins in inventions 1792-2034 does not reveal art for detection of each of the polynucleotides 1-516 or each of the polypeptides 1-243 as in inventions 2035-2794.

In addition, each of these inventions 1-2794 can be carried out using each one of the 1-516 polynucleotides recited in claim 1, or the polypeptides selected from 1-243 recited in claims 2, and 14, thereby generating multiple patentable inventions. Therefore, the Applicant is advised

that no matter which group is elected, the Applicant is required to specify one specific nucleotide or polypeptide for examination. This requirement is made under 1192 O.G.68 Notice (November 19, 1996), as examination of more than one sequence in one application would result in an undue burden on the PTO.

These inventions are distinct for the reasons given above, and they have acquired a separate status in the art shown by their recognized divergent subject matter. Therefore, search for each of these inventions would not reveal art for the other. Thus, the Examiner has *prima facie* shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

***Election of Species:***

The ligands recited in claims 9 and 16 can be the following patentably distinct species of the claimed invention: DNA molecules, RNA molecules, PNAs, mimetics, peptides, proteins, agonists, antagonists, antibodies or their fragments, immunoglobulins, inhibitors, drug compounds, and pharmaceutical agents.

Applicant is required under 35 U.S.C.121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable. Currently claims 9 and 16 are generic.

The method of screening/detecting pro-inflammatory disorders and anti-inflammatory disorders listed in claims 19-20 also comprise patentably distinct inventions: viral infections, rheumatoid arthritis, insulin-dependent diabetes mellitus, multiple sclerosis, encephalomyelitis, inflammatory bowel disease, psoriasis, pemphigus vulgaris, bacterial and parasitic infections,

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allergies and other atopic disorders, chronic graft versus host disease, scleroderma, and systemic lupus erythematosus.

Applicant is required under 35 U.S.C.121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable. Currently claims 19, 20 are generic.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

*Advisory Information*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarada C Prasad whose telephone number is 703-305-1009. The examiner can normally be reached Monday – Friday from 8.00 AM to 4.30 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sarada Prasad, Ph.D.  
Examiner Art Unit 1646  
April 16th, 2001

*Prema Mertz*  
PREMA MERTZ  
PRIMARY EXAMINER